UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Criminal No.** 1:24CR46
	)	
MCKINSEY & COMPANY, INC. UNITED STATES	)	

AGREED STATEMENT OF FACTS

I. Organization of McKinsey & Company, Inc., United States and work with Purdue Pharma, L.P.

1. The defendant, McKinsey & Company, Inc. United States (MCKINSEY) is a Delaware corporation with its principal place of business in New York, New York. MCKINSEY is an indirect wholly owned subsidiary of McKinsey & Company, Inc. (McKinsey Inc.), a New York Corporation. McKinsey Inc. is a global management consulting firm, founded in 1926 in Chicago, Illinois and with offices in over 130 cities in more than 65 countries.

2. MCKINSEY supports private sector clients throughout the United States. MCKINSEY recruits consultants with a wide variety of backgrounds including from the most elite universities in the world. MCKINSEY consultants often work directly with clients' senior management (C-Suite) and boards of directors.

3. MCKINSEY is organized into practice groups led by senior partners of the firm. One of these was the firm's Pharmaceutical and Medical Products (PMP) practice. For years, MCKINSEY worked with several pharmaceutical companies concerning their manufacture and sale of opioids, including Purdue Pharma L.P., Company 1, Company 2, and Company 3. Between 2004 and 2019, MCKINSEY contracted with Purdue Pharma L.P. on 75 different engagements in the United States.

4. Purdue Pharma L.P. is a U.S.-based, privately held pharmaceutical limited partnership, established in Delaware with its principal place of business in Connecticut (together with its affiliates, "Purdue Pharma"). Purdue Pharma manufactured, distributed, and sold the extended-release opioid drugs OxyContin, Butrans, and Hysingla. Purdue Pharma sales representatives marketed these drugs through in-person sales calls until in or about February 2018, when Purdue Pharma laid off the bulk of its sales force and ceased all in-person opioid marketing, although it continues online marketing and offers prescription savings cards for OxyContin and other opioid products to this day.

5. OxyContin is an extended-release oxycodone tablet. Oxycodone is an opioid agonist with a morphine milligram equivalent (MME) of 1.5 and a high potential for abuse.[1] Oxycodone is a Schedule II narcotic controlled substance.

6. In 1995, OxyContin was approved by the United States Food and Drug Administration (FDA) for the "management of moderate to severe pain in patients who

[1] MME is a value that represents the potency of an opioid dose relative to morphine.

require treatment with an oral opioid analgesic for more than a few days." In 2001, FDA approved a revised label for OxyContin, noting OxyContin "is intended for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time."

7. A report that Purdue Pharma authored and shared with MCKINSEY in July 2009 stated that OxyContin "currently accounts for 34% of opioid scripts in the US. However, generics are exerting pressure on branded products such that OxyContin is losing share at a rate of 2 points per year."

8. In 2010, OxyContin was reformulated with abuse-deterrent properties. MCKINSEY worked with Purdue Pharma to obtain approval of the abuse-deterrent formulation by the FDA. The label still noted OxyContin's ongoing abuse liability, that it could be abused, and was subject to criminal diversion. ("OxyContin contains oxycodone, which is a Schedule II controlled substance with an abuse liability similar to morphine. OxyContin, like morphine and other opioids used for analgesia, can be abused and is subject to criminal diversion.")

9. In April 2013, the FDA approved new labeling for OxyContin. The revised OxyContin label read: "OxyContin is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment where alternative treatment options are inadequate" and indicated "the product has physical and chemical properties that are expected to make abuse by injection difficult and to reduce abuse via the intranasal route." The label further noted, however: "[a]buse may occur by taking intact tablets in

quantities greater than prescribed or without legitimate purpose, by crushing and chewing or snorting the crushed formulation, or by injecting a solution made from the crushed formulation . . . . The data from the clinical study, along with support from the in vitro data, also indicate that OxyContin has physicochemical properties that are expected to reduce abuse via the intranasal route. However, abuse of OxyContin by these routes, as well as by the oral route is still possible." When MCKINSEY received news that the FDA had approved the revised label, a MCKINSEY consultant sent an email to another MCKINSEY consultant saying "[w]e did it."

10. At all relevant times, the sale of OxyContin was approved by the FDA, and it was lawful for licensed medical professionals to prescribe OxyContin to patients for only a medically valid purpose. OxyContin continues to be a prescription drug that is sold lawfully in the United States. Prescribing OxyContin for illegitimate purposes fueled the opioid crisis and continues to be a public health problem in the United States.

II. The FDA and the Food, Drug, and Cosmetic Act

11. The FDA is responsible for protecting the health and safety of the American public by ensuring, among other things, that pharmaceutical drugs are safe and effective for their intended uses and bear labeling that contains true and accurate information. The FDA regulates the manufacturing, labeling, and distribution of medical devices shipped or received in interstate commerce and enforces the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (FDCA).

12. The FDCA prohibits, among other things, the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 331(a).

13. The FDCA defines labeling to include "all labels and other written, printed, or graphic matter . . . accompanying [a drug]." 21 U.S.C. § 321(m).

14. The FDCA provides that a drug is misbranded "[i]f its labeling [was] false or misleading in any particular." 21 U.S.C. § 352(a). The FDCA further provides that "[i]n determining whether the labeling . . . [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use . . . to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual." 21 U.S.C. § 321(n).

15. OxyContin was a drug within the meaning of the FDCA. 21 U.S.C. § 321(g)(1).

III. MCKINSEY's engagements with Purdue Pharma

16. From approximately 2002 to 2003, Purdue Pharma was the subject of a public congressional investigation related to abuse and diversion of OxyContin. In December 2003, the General Accounting Office (GAO) issued findings that, among other things, Purdue Pharma's marketing of OxyContin was overly aggressive and exacerbated

OxyContin's abuse and diversion. The GAO's report also explained that "OxyContin is the most abused single-entity prescription product according to those DEA state and divisional offices that report OxyContin abuse." The report further stated, in part, that "DEA field offices continue to report OxyContin as a drug of choice among abusers." It also stated, "[w]e agree with DEA that Purdue conducted an extensive campaign to market and promote OxyContin using an expanded sales force and multiple promotional approaches to encourage physicians, including primary care specialists to prescribe OxyContin as an initial opioid treatment for noncancer pain, and that these efforts may have contributed to these problems. We also agree that Purdue marketed OxyContin as having a low abuse liability, but we noted that this was based on information in the original label approved by FDA."

17. Shortly thereafter, in 2004, MCKINSEY and Purdue Pharma executed a Master Consulting Agreement, which formed the basis of MCKINSEY's retention as a consultant for Purdue Pharma. Thereafter, for each engagement or project, the parties executed a Statement of Services to the Master Consulting Agreement that detailed the specific terms and plan for each individual project, including project objectives and deliverables. As an outside consultant, MCKINSEY advised Purdue Pharma regarding what steps Purdue Pharma should take in connection with each particular engagement.

18. Over the course of 75 engagements from 2004 through 2019 and against the backdrop of a nationwide opioid crisis, MCKINSEY worked with Purdue Pharma on a variety of topics, including how to improve revenues from OxyContin and later

reformulated OxyContin, achieve cost reductions, develop an M&A strategy, improve R&D redesign, and enhance organizational governance and management. Purdue Pharma, in turn, paid MCKINSEY approximately $93,546,499 (ninety-three million five hundred forty-six thousand four hundred ninety-nine dollars) over that fifteen-year period.

19. On or about February 9, 2004, two months after the GAO findings, MCKINSEY presented an outline of a proposal to Purdue Pharma entitled, "Purdue's Imperative – Defining a Future of Growth." In that outline, MCKINSEY noted to Purdue Pharma that they had "been on the ground for ~10 days" and had "a better perspective on how [MCKINSEY] might help [Purdue Pharma]." MCKINSEY advised Purdue Pharma to "refocus" on a list of priority items, including "agree[ing] on a set of targeted deep dives to resolve key strategic issues, redesign[ing] selected processes or driv[ing] cost savings in specific areas." Among these was "[d]riving OxyContin performance (resetting targets and coverage model, creating segment-specific messaging and materials)."

20. As of February 2004, Purdue Pharma was the subject of federal and state criminal and civil investigations.

21. During the time MCKINSEY served as a consultant for Purdue Pharma, MCKINSEY worked closely with Purdue Pharma leadership. At times, MCKINSEY consultants interacted directly with Purdue Pharma's board of directors (Purdue Pharma Board), which was dominated by one family (the Family). MCKINSEY consultants had high-level access to employees at Purdue Pharma; occupied office space at Purdue Pharma's headquarters in Stamford, Connecticut, down the hallway from the Family and

C-Suite; and went on several "ride-alongs" with Purdue Pharma sales representatives, accompanying them on sales calls to potential and then-current prescribers of OxyContin. MCKINSEY consultants and Purdue Pharma worked side by side to develop marketing messages and increase OxyContin sales, including by using data analytics.

22. MCKINSEY knew the risks and dangers associated with OxyContin, a powerful and addictive opioid. MCKINSEY also knew that Purdue Pharma's affiliate and its top executives had previously pled guilty to federal crimes relating to the marketing and promotion of OxyContin. Nevertheless, MCKINSEY chose to continue working with Purdue Pharma to improve sales of OxyContin, among other engagements.

23. In fact, between 2013 and 2014, MCKINSEY designed strategies to help Purdue Pharma identify which prescribers the Purdue Pharma sales force should call on to increase OxyContin prescriptions. This included a strategy to identify which current OxyContin prescribers (referred to as High Value Prescribers) would likely generate the greatest number of additional prescriptions if called on by Purdue Pharma's sales force. MCKINSEY recommended the use of factors including the existing volume of OxyContin prescriptions, historic preference for generic drugs, willingness to change from one brand of drug to another, and medical specialty to identify High Value Prescribers. Focusing sales calls on High Value Prescribers resulted in reformulated OxyContin prescriptions for uses that were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and that were often diverted for uses that lacked a legitimate medical purpose. MCKINSEY recommended and worked with Purdue Pharma to implement a plan to detail

these High Value Prescribers, some of which were writing 25 times as many reformulated OxyContin prescriptions as similarly situated peers, because it knew that detailing these prescribers was effective in producing more reformulated OxyContin prescriptions, thereby increasing Purdue Pharma's revenue.

IV. MCKINSEY's knowledge of Purdue Pharma's 2007 criminal conviction

24. In 2007, a Purdue Pharma affiliate company pled guilty to misbranding OxyContin, from 1996 through 2001, by falsely marketing it as less addictive, less subject to abuse and diversion, and less likely to cause dependence and withdrawal than other pain medications. Purdue Pharma and its affiliate also agreed to pay more than $600 million, of which more than $100 million was paid to settle civil False Claims Act liability for knowingly causing the submission of false claims to federal healthcare programs for OxyContin. In addition, Purdue Pharma's then president, general counsel, and medical director each pled guilty to misbranding in violation of the FDCA, a criminal offense, and collectively paid a total of $34.5 million in monetary penalties. During engagements, each of those executives had offices near the conference room where MCKINSEY employees were stationed at Purdue Pharma's headquarters.

25. As part of the 2007 criminal resolution, Purdue Pharma also entered a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services, Office of the Inspector General (HHS-OIG). During its term, the CIA placed restrictions on Purdue Pharma's sales and marketing of OxyContin. Purdue Pharma

determined that some MCKINSEY consultants were "Responsible Covered Persons" under, and therefore subject to, the terms of the CIA.

26. After the 2007 guilty pleas of the Purdue Pharma affiliate and certain executives, MCKINSEY partners maintained close contact with Purdue Pharma. In an email dated June 22, 2007, MCKINSEY Senior Partner 1 wrote to other MCKINSEY partners, including MCKINSEY Senior Partners 2 and 3, about Purdue Pharma: "[M]any touches over past few weeks/months…mxf [*sic*] – [referring to then Purdue Pharma CEO Michael Friedman] setting up introduction meeting with new ceo… ."

V. MCKINSEY worked with Purdue Pharma to prepare draft REMS

27. In 2007, Congress enacted legislation allowing the FDA to require Risk Evaluation and Mitigation Strategies (REMS) for prescription drugs with addictive properties to ensure the benefits of those drugs outweigh the risks.

28. MCKINSEY knew that if the FDA created a REMS with restrictive requirements for opioids, a significant decline of OxyContin sales could result.

29. The FDA began to require REMS for various drugs starting in March 2008. Before the FDA required Purdue Pharma to submit a REMS for its abuse deterrent formulation of OxyContin in late 2008, the FDA had never required a REMS for an opioid drug.

30. On or about October 3, 2008, the FDA sent a letter to Purdue Pharma outlining the required elements for a proposed REMS by Purdue Pharma, including a

Medication Guide, Elements to Assure Safe Use (ETASU), an implementation system, a communication plan, and a timetable for assessments.

31. In an October 2008 confidential memorandum for Purdue Pharma's CEO (Purdue Pharma Executive 1), MCKINSEY outlined its efforts to "work with your core team to partner with them to develop their respective sections of the REMS plan." MCKINSEY wrote: "The FDA's increasingly risk conservative position, has resulted in REMS requirements across indications. For controlled substances, recent communications recommend that the FDA take a broader approach in examining opioids as an entire class. Our interpretation is that this is an aggressive attempt by the agency to address diversion, abuse, and misuse (e.g., high dosages to opioid naïve patients). The potential complication of the approach is that it may unduly limit access to patients who need pain relief." MCKINSEY proposed working with Purdue Pharma to "[d]evelop a fact base and business case that is most effective in meeting [Purdue Pharma's] common objectives with the [FDA] – to ensure appropriate use by patients and to prevent access by non-patients."

32. On October 23, 2008, MCKINSEY Consultant 1 emailed MCKINSEY's Senior Partners 1 and 2 about MCKINSEY's work with Purdue Pharma, including on the REMS. MCKINSEY Consultant 1 relayed that she had spoken with Purdue Pharma's CEO who was "aware of the critical role we are playing in pulling REMs together and is very appreciative." MCKINSEY Consultant 1 also noted that two Purdue Pharma Board members had approached a member of Purdue Pharma leadership and "'blessed' him to do whatever he thinks is necessary to 'save the business.'" As for Purdue Pharma's broader

strategy, MCKINSEY Senior Partner 1, MCKINSEY Senior Partner 2 and MCKINSEY Consultant 1 emailed about the importance of "get[ting] to the board." MCKINSEY Senior Partner 2 emailed Senior Partner 1, "[Senior Partner 1] maybe you can just call [Family Member 1] and see how he is feeling."

33. As part of its work to advise Purdue Pharma on the development of the REMS, MCKINSEY noted it was going to flesh out two REMS variants: "Option A: literal version which follows exactly what the FDA has stated in their letter" or "Option B: 'to the spirit' version, which follows the letter where possible, but where it becomes problematic, go for something that's in line with the spirit of what the FDA is asking for."

34. The FDA adopted the less restrictive REMS that resulted in high-dose OxyContin remaining subject to the same oversight as lower dose opioids. It further prevented a moratorium on extended-release opioids. The REMS additionally made training for prescribers voluntary and not mandatory.

35. On October 31, 2008, MCKINSEY prepared the first draft of the proposed REMS for OxyContin, which included all elements required by the FDA: (1) a draft medication guide explaining the benefits and risks of OxyContin that Purdue Pharma would distribute to providers to give to every patient prescribed OxyContin; (2) required training for providers and patients; (3) required certification in a program called PROVIDE (Purdue's Responsible Opioid Verification, Intervention, Dispensing, and Evaluation), which was intended to teach prescribers about OxyContin and risk management; (4) a certification program in which prescribers, dispensers, and patients had to be enrolled and

certified in order to prescribe, dispense, or receive OxyContin; (5) training or education about proper use and an attestation of receipt and understanding of that training; (6) a communication plan to support implementation of the REMS program, which required Purdue Pharma to provide a letter and other educational materials to healthcare providers; (7) databases of certified prescribers, dispensers, and patients maintained by Purdue Pharma; and (8) a timeline for submitting assessments at 18 months, 3 years, and 7 years following approval, and every 4 years thereafter.

36. On November 5, 2008, MCKINSEY convened a "blue ribbon panel" of independent experts to discuss REMS for reformulated OxyContin, including consultants, doctors, regulatory professionals, and academics to advise on REMS for Purdue Pharma's proposal to the FDA. The panel suggested that having a coalition of industry participants working together to develop uniform REMS would be beneficial for the entire medical industry, including patients.

37. On November 14, 2008, in a public meeting unrelated to OxyContin, the Director of the Division of Anesthesia, Analgesia, and Addiction Products at the FDA stated that the FDA was "still in the infancy of understanding what our authorities are under the new law in regard to REMS . . . the one clear voice that we have on this is that it really would be appropriate to have all the companies who have potent opioids work together to have some type of REMS program."

38. On December 4, 2008, days before Purdue Pharma was scheduled to submit its already finalized proposed individual REMS, the FDA sent a letter to Purdue Pharma

requesting that Purdue Pharma not submit REMS while the FDA considered class-wide REMS—a uniform program for all products in a drug class.

39. On March 3, 2009, the FDA met with manufacturers of extended release and long-acting opioid medications to discuss the requirement for a class-wide REMS. In response, 25 branded and generic pharmaceutical companies that marketed long-acting and extended-release opioids formed a consortium, called the Industry Working Group (IWG), to develop and propose industry-wide REMS for the class of Extended Release/Long-Acting opioids, including reformulated OxyContin.

40. MCKINSEY later provided technology support to Purdue Pharma relating to the implementation of REMS but did not provide technology support to the IWG.

41. The FDA approved the final class-wide REMS on July 9, 2012. The FDA ultimately adopted the IWG's REMS, which was different from what MCKINSEY originally proposed. For example, unlike the proposed REMS drafted by MCKINSEY, the adopted class-wide REMS did not include any communication plan, certification, verification, patient registry, or database of certified prescribers, dispensers, and patients.

VI. MCKINSEY worked with Purdue Pharma to enhance "Brand Loyalty" for OxyContin and protect market share

42. On May 25, 2009, Purdue Pharma engaged MCKINSEY to "help protect, defend and accelerate OxyContin performance at a time of change, including the new formulation launch and new competitor entry." According to the contract between MCKINSEY and Purdue Pharma, this effort was focused on developing a "set of messages

and tactics for OxyContin to: Reduce and potentially turnaround the recent volume and share decline[;] Enhance loyalty to OxyContin among loyalist prescribers[;] Convert 'fence sitters' into more loyal OxyContin prescribers[;] Capture full in-label potential of new formulation among appropriate patients[; and] Protect OxyContin's market share against new market entrants[.]"

43. MCKINSEY's deliverables for the project included: "Understanding of drivers of recent decline in category size and market share," "Brand positioning (target segments, frame of reference, reason for differentiation) to maintain and enhance brand loyalty in appropriate patients," and "List of customer issues about new formulation and potential approaches to mitigate concerns[.]"

44. In July 2009, MCKINSEY prepared a confidential memorandum for Purdue Pharma Executive 1 with ideas to "chart the course for the 'New [Purdue Pharma].'" MCKINSEY wrote that "[Purdue Pharma] must … drive the OxyContin franchise[.]" MCKINSEY wrote that "driving a more impactful OxyContin franchise should be your top priority." MCKINSEY advised Purdue Pharma to create a small working group to, among other things, "[e]nsure everything is done to optimize and protect OxyContin's positioning[.]" Purdue Pharma should "[b]alance the drive for outsized growth and profitability against the potential for increased regulatory scrutiny and/or compromised exclusivity; adjust sales and marketing plans appropriately[.]" The memo concluded: "It has been our distinct privilege to play a small part in [Purdue Pharma's] progress."

45. In an email dated July 7, 2009, concerning a "Brand Loyalty Project" for OxyContin, Purdue Pharma Executive 2 wrote to MCKINSEY: "I want to be clear that the overall goal of this project is to provide us with recommendations on what we should be doing to support OxyContin (current and new formulation) from both a sales and marketing perspective… regardless of what we think legal may or may not say. The only exception here is what we would test from a messaging perspective." He added: "At the appropriate time, we will have all the necessary conversations with med, reg, and legal to make sure we are promoting the product within FDA regulations."

46. In a "brand loyalty" presentation to Purdue Pharma dated September 11, 2009, MCKINSEY presented its findings on "drivers" of brand loyalty, including "opportunities" to promote messages to make prescribers more comfortable prescribing OxyContin. MCKINSEY identified "issues" with OxyContin's brand, including: "Has a reputation for being abused and diverted" and "[i]s medication patients are reluctant to take."

47. MCKINSEY laid out for Purdue Pharma "[p]otential reasons why greater number of patients are discontinuing use of [OxyContin] and opioids," including: "Physician and patient perceptions of OER [oxycodone extended-release] is changing (e.g., concerns about)." In an effort to address these negative perceptions, MCKINSEY proposed to "interrogate physicians through phone and in-depth interviews."

48. Based on its research concerning the negative perceptions and to improve sales, MCKINSEY developed a "Physician Segmentation" initiative to target specific

messages to specific prescribers of OxyContin—that is, to tailor Purdue Pharma's messaging to increase OxyContin prescriptions. MCKINSEY divided prescribers into four different segments.

49. In documents shared with Purdue Pharma, MCKINSEY emphasized that the group of prescribers it characterized as "Chronic Pain Avoiders" should be urged by Purdue Pharma salespeople to "promote ER usage in opioid naïve patients and to step up to ER while maintaining share."

50. "Opioid naïve" meant patients who were being put on opioids for either the first time or the first time after a certain period. In other words, MCKINSEY advised Purdue Pharma on how to encourage prescribers to issue prescriptions to patients who were not currently using OxyContin.

51. Following its previous guidance, in November 2009, MCKINSEY issued a report recommending Purdue Pharma sales representatives "emphasiz[e] [the] broad ranges of doses." Higher milligram OxyContin tablets generated the most revenue for Purdue Pharma.

52. MCKINSEY estimated that these new sales and marketing steps would result in $200 million to $400 million more in revenue for Purdue Pharma. This plan was introduced to the Purdue Pharma sales force at the National Sales Meeting in January 2010.

VII. MCKINSEY worked with Purdue Pharma to obtain approval for reformulated OxyContin

53. Meanwhile, in 2010, while the CIA was in effect, MCKINSEY worked with Purdue Pharma to obtain FDA approval for a reformulated version of OxyContin.

54. At the time, development of abuse deterrent formulations was a priority for the FDA, State Attorneys General, and other public health authorities. For example, an April 2011 White House report committed the government to expediting research on the development of abuse deterrent formulations of opioids through grants, partnerships with academic institutions, and priority New Drug Application review by the FDA. The government further committed, through the FDA, to providing guidance to the pharmaceutical industry on the development of abuse deterrent drug formulations and on post-market assessment of their performance.

55. Similarly, in March 2013, 48 State Attorneys General wrote to the FDA Commissioner urging the FDA to encourage manufacturers to make abuse deterrent versions of their opioids, because they could "be part of a comprehensive approach" to combating abuse. Later, in December 2013, after the approval of the reformulated version of OxyContin, 42 State Attorneys General wrote to the FDA thanking the FDA for its "recent efforts to ensure branded opioid drugs have abuse-deterrent formulations."

56. Purdue Pharma's reformulated OxyContin included abuse-deterrent properties, including an added ingredient that was designed to make the pill more difficult to crush or dissolve, and therefore less likely to result in an overdose when tampered with. Purdue Pharma claimed, and the FDA ultimately agreed, this made it more difficult, but not impossible, to abuse OxyContin by dissolving a pill and injecting the drug.

57. Reformulated OxyContin also served an additional purpose for Purdue Pharma: modifications to existing patented pharmaceutical products can result in extended patent protection, which would allow Purdue Pharma to reduce competition from generic versions of OxyContin (which lacked these new abuse-deterrent properties).

58. In 2008, Purdue Pharma failed to secure the FDA's approval of its application for reformulated OxyContin. Purdue Pharma thereafter retained MCKINSEY to define a strategy and prepare it for critical meetings with the FDA Advisory Committee in its second attempt to obtain approval for reformulated OxyContin. As part of its engagement, MCKINSEY helped Purdue Pharma develop more rigorous testing to, among other things, assess the physical characteristics of reformulated OxyContin to evaluate tampering with the new formulation, which Purdue Pharma ultimately provided to the FDA in support of its new drug application.

59. To demonstrate the abuse deterrent properties of the reformulated OxyContin, MCKINSEY proposed testing various real-world crushing methods such as use of a pill crusher, mortar and pestle, grater, spice grinder, hammer, food processor, among others, identifying the particle size distribution associated with each, and its corresponding likelihood of abusability. MCKINSEY's proposed testing plan also included evaluating the effects of temperature changes and the use of various household solvents such as orange juice, cooking oil, coffee, and alcohol on the new formulation.

60. The second FDA Advisory Committee meeting was in September 2009. In advance of the meeting, Purdue Pharma resubmitted its new drug application for

reformulated OxyContin, along with the results of the testing plan proposed by MCKINSEY.

61. In preparation for the Advisory Committee meeting, MCKINSEY met with a former FDA official who served Purdue Pharma as an expert advisor who advised Purdue Pharma that they needed to find a way to counter the emotional messages from their "toughest critics," such as "emotional messages from mothers with teenagers that overdosed in [*sic*] OxyContin" with equally emotional and compelling messages, "e.g., a husband who's [*sic*] wife has metastatic bone cancer who needs OxyContin for her extreme pain."

62. MCKINSEY met with Purdue Pharma executives and members of the Family to prepare for the second FDA Advisory Committee meeting. MCKINSEY Consultant 1 wrote in an email: "[We had] [Purdue Pharma's Chief Medical Officer] up for 2 hour working session with our FDA expert . . . it was extremely helpful to get insights on how they are crafting our response." She further noted they had done a "rehearsal with several family members present" and that Family Member 1 was "impressed."

63. MCKINSEY's efforts paid off. In or around April 2010, the FDA approved reformulated OxyContin, while cautioning that reformulated OxyContin "is not completely tamper-resistant and those intent on abusing this new formulation will likely find a means to do so. In addition, the product can still be misused or abused and result in overdose by simply administering or ingesting larger than recommended oral doses." Indeed, studies that MCKINSEY reviewed showed that OxyContin was most commonly abused orally.

The FDA, Purdue Pharma, and MCKINSEY knew that reformulated OxyContin would not be a panacea, but the FDA approved the reformulation because evidence showed that it would be an "improvement over the market."

64. In August 2010, Purdue Pharma discontinued the original version of OxyContin with the intent of only selling reformulated OxyContin going forward. Because it was a "new drug," no generics could be made of reformulated OxyContin, giving reformulated OxyContin new exclusivity in the market.

VIII. Sales immediately declined following the introduction of reformulated OxyContin; focus on "Region Zero" prescribers

65. Following the introduction of reformulated OxyContin in August 2010, OxyContin sales immediately began to decline. Purdue Pharma studied the drivers for this decline and attributed it, in large part, to a drop in prescriptions for individuals who were abusing OxyContin and increases in safeguards intended to hinder medically unnecessary prescribing of OxyContin.

66. Purdue Pharma annually applied for and received registrations from the U.S. Drug Enforcement Administration (DEA) as a manufacturer and distributor of controlled substances. Accordingly, Purdue Pharma was subject to the obligations imposed by the Controlled Substances Act and its implementing regulations, including the requirement that it maintain effective controls against diversion. To identify prescribers engaged in abuse and diversion, Purdue Pharma implemented an Abuse and Diversion Detection

Program (ADD Program), which included a list of prescribers that Purdue Pharma determined its sales representatives should cease calling on (Region Zero).

67. According to Purdue Pharma documents, as of 2009, 40% of Purdue Pharma's revenue from OxyContin came from prescriptions for the 80 mg strength. According to analysis performed by Purdue Pharma's sales staff, as of December 22, 2010, prescribers assigned to Region Zero accounted for a 75% decline in 80 mg prescriptions comparing six-week periods before and after reformulated OxyContin. Region Zero prescribers are those prescribers that Purdue Pharma's sales representatives were not supposed to call on because Purdue Pharma had determined those providers were likely sources of abuse or diversion.

68. A later Purdue Pharma document attributed approximately 40% of the decline in 2010 and 2011 to Region Zero prescribers. A Purdue Pharma study showed that for the time period from August 2009 to July 2011, there was an 86% decline in OxyContin prescriptions by Region Zero prescribers after the switch to reformulated OxyContin, especially at the highest doses, 40 and 80 mg tablets.

69. Purdue Pharma tracked Region Zero prescribers through its ADD Program. Purdue Pharma's ADD Program identified characteristics of suspicious prescribers that required the Purdue Pharma salesforce to identify such prescribers to its Law Department by initiating a Report of Concern (ROC). After review of the ROC, the Law Department determined whether to place the prescriber on the Region Zero list. MCKINSEY had no oversight of the ADD Program, including the ROCs or Region Zero list.

70. Purdue Pharma had detailed information (down to the number of prescriptions written, product, and dosage) of its products prescribed by all prescribers, including Region Zero prescribers. On April 20, 2010, as part of the geospatial engagement (discussed below), Purdue Pharma shared the existing list of Region Zero prescribers and the ADD Program Standard Operating Procedures with MCKINSEY. On October 11, 2010, Purdue Pharma shared all ROCs concerning prescribers who were suspected of facilitating abuse of OxyContin. MCKINSEY consultants noted the ROCs were "a fascinating read" and gave a "great sense of some of the pathways of abuse."

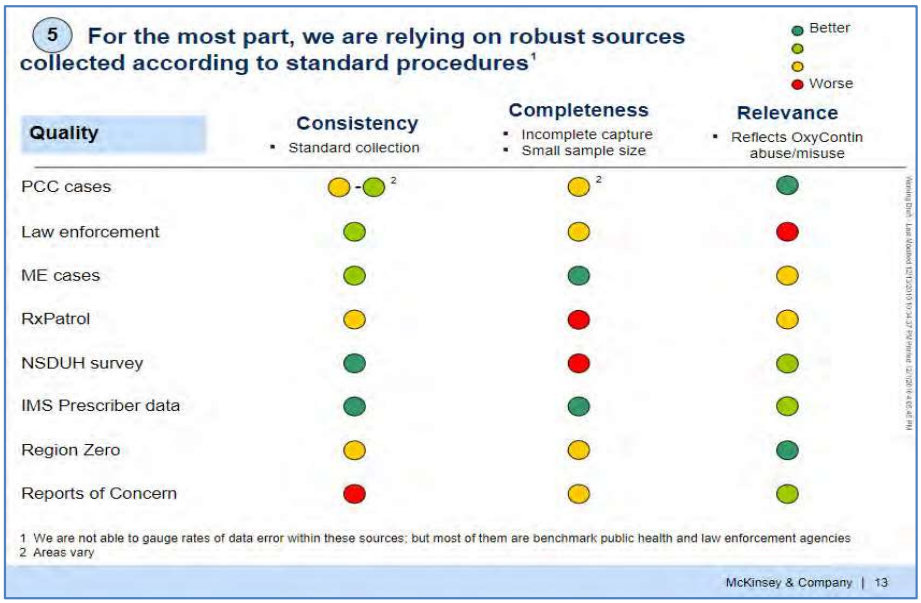
71. Purdue Pharma's Region Zero list and ROCs were incomplete as they failed to capture the full extent of prescribers engaged in abuse and diversion of OxyContin.

IX. MCKINSEY conducted geospatial analysis of abuse and diversion of OxyContin for Purdue Pharma

72. MCKINSEY was aware Region Zero had limitations because, following the introduction of reformulated OxyContin, Purdue Pharma engaged MCKINSEY to conduct an analysis of OxyContin abuse and diversion.

73. In 2010, Purdue Pharma brought in a team from MCKINSEY to do a "geospatial" analysis of abuse and diversion of OxyContin: analyzing data on OxyContin abuse (including overdoses) and where increased levels of OxyContin abuse were occurring for the purpose of being able to develop a model to predict and prevent further abuse and diversion.

74. Using several sources of data, MCKINSEY analyzed where "OxyContin abuse/misuse" was occurring, as shown on the following slide from a MCKINSEY presentation to Purdue Pharma:



75. As shown on the above chart, MCKINSEY understood that the "consistency" and "completeness" of data on abuse from Region Zero was towards the "worse" end of the scale—in other words, that Region Zero was incomplete in terms of data for identifying OxyContin abuse.

76. MCKINSEY identified IMS Prescriber data as being on the "better" end of the scale as to consistency, completeness, and relevance for identifying where OxyContin abuse/misuse was occurring. IMS Prescriber data referred to data commercially available from IMS Health. MCKINSEY would later use IMS Prescriber data to identify high prescribers as part of a sales and marketing engagement to "turbocharge" the OxyContin sales pipeline.

77. During the geospatial engagement, Purdue Pharma provided MCKINSEY with granular data on OxyContin abuse, including a summary of "all of the ROCs" submitted by Purdue Pharma sales representatives in the field between 2005 and 2010. In an email dated December 17, 2010, the lead MCKINSEY consultant on the geospatial project, MCKINSEY Consultant 2, commented to her counterparts at Purdue Pharma that individual IMS Prescriber data "allowed us to identify the top prescribers, and it was interesting to observe what a high proportion of total prescribing came from relatively few doctors (some of them pain specialists, no doubt; but others for unclear reasons – the data also gave their specialty)."

78. In or about April 2011, MCKINSEY submitted Phase 2 of the geospatial study to Purdue Pharma, which attempted to identify geographic areas where the risk of abuse was high, and which would merit attention from Purdue Pharma to mitigate those risks. Although the data allowed MCKINSEY to get to a more granular level, it was not as temporally sensitive as MCKINSEY had hoped but still was an improvement over Purdue Pharma's then current surveillance techniques. This Phase 2 was sent to Purdue Pharma's then Chief Medical Advisor.

79. On September 9, 2011, the Purdue Pharma Medical Advisor emailed MCKINSEY a copy of a Purdue Pharma presentation titled, "Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion?"

80. The "hypothesis" for this study was that "Reformulated OxyContin" was more difficult to manipulate for purpose of abuse, leading to reduced demand from abusers,

thus leading to "Reduced Diversion." Under the heading "Changes in prescription patterns consistent with diversion," the presentation noted five points:

a. "Temporal association with transition to reformulated OxyContin"

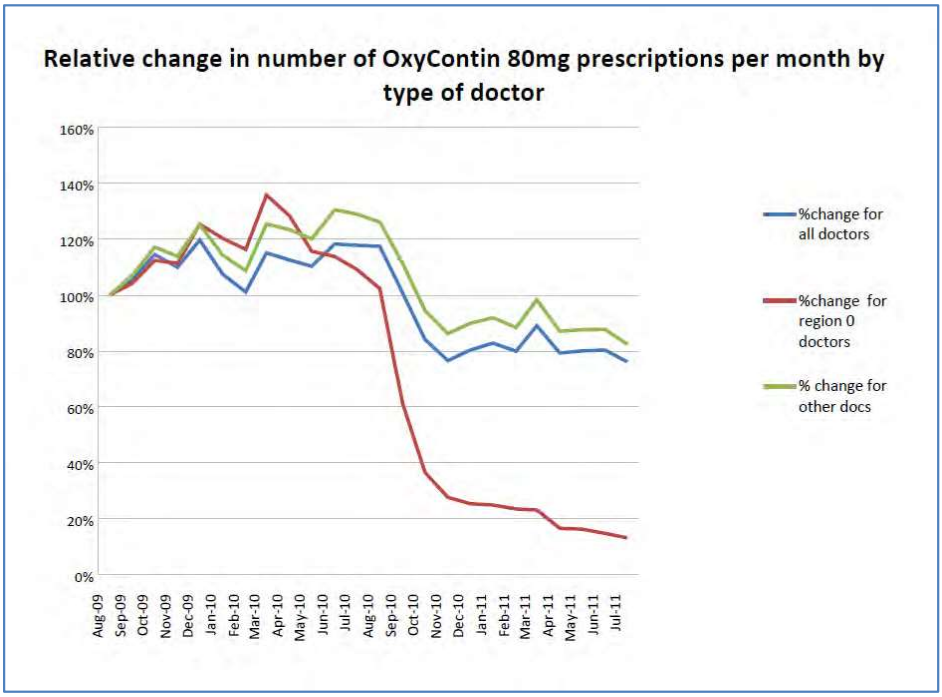
b. "Greater declines for high versus low dosage strengths"

c. "Greater declines for cash versus other payment types"

d. "Greater declines for doctors suspected of questionable prescribing"

e. "Increases in supply of original OxyContin"

81. The presentation showed that a decline in prescriptions by Region Zero doctors accounted for a disproportionate percentage of the drop in OxyContin prescriptions, especially at the 80 mg level:



82. The remainder of the decline, however, was caused by similarly steep declines in prescriptions among high prescribers that Purdue Pharma continued to detail.

83. While it appeared that certain Purdue Pharma executives may have wanted to go forward with Phase 3 of the geospatial project, which would allow MCKINSEY to get to a granular level on the abuse data, there was an issue with Purdue Pharma getting specific IMS Prescriber data for MCKINSEY. In or about March 2012, Purdue Pharma shelved MCKINSEY's geospatial analysis of OxyContin abuse and diversion, and the engagement ended without MCKINSEY proposing any new measures to track or predict patterns of abuse.

X. After the CIA expired, Purdue Pharma engaged MCKINSEY to recover lost OxyContin sales

84. After abandoning the geospatial analysis of OxyContin abuse and diversion, Purdue Pharma's attention turned to ways of increasing OxyContin prescriptions to counter the loss of prescriptions after the introduction of reformulated OxyContin. Purdue's own study had determined those lost prescriptions showed indicia "consistent with diversion." Once again, Purdue Pharma turned to MCKINSEY.

85. Purdue Pharma's CIA that resulted from the 2007 conviction was originally set to expire in July of 2012. In the spring of 2012, MCKINSEY and Purdue Pharma began to discuss potential engagements to evaluate the underlying drivers of OxyContin's performance and identify new opportunities for increasing sales.

86. In an internal Purdue Pharma email dated April 15, 2012, Family Member 1 emailed Purdue Pharma Executive 4 and wrote, "We should also discuss the sudden decline in OC sales in the past year or two. What are we doing to identify ***corrective actions***?" (Emphasis added.)

87. Four days later, MCKINSEY Senior Partner 1 sent a proposal to Purdue Pharma Executive 9 concerning an "opportunity identification for OxyContin." The proposal described how "McKinsey would conduct a rapid diagnostic of the underlying drivers of OxyContin's current performance and develop hypotheses on specific opportunities [Purdue Pharma] should consider." Purdue Pharma Executive 9 responded the following day with "a few comments," including one which read, "The 5 Year Corporate Integrity Agreement expires in July. What impact, if any, will that have on our commercial practices while maintaining strict compliance?" MCKINSEY revised the proposal to incorporate some of the comments from Purdue Pharma Executive 9. In the revised proposal, under "Build hypotheses on levers to improve performance," it stated: "Understand if any new options available in near future with expiry of Corporate Integrity agreement[.]" Subsequent written versions of the proposal and the scope of work did not include this language.

88. The CIA expired in January 2013.

89. That same month, in January 2013, MCKINSEY Senior Partner 3 reached out to MCKINSEY Senior Partners 1 and 2 to check on the status of the previous conversations with Purdue Pharma Executive 1 about "his openness to our support."

90. In an email dated January 23, 2013, MCKINSEY Senior Partner 2 responded: "Your note is timely. [MCKINSEY Senior Partner 1] and I are with [Purdue Pharma Executive 1] for the first time in a long time on Friday. It is clear that public pressure (and government) on oxy continues to mount . . . ."

91. In an email dated January 25, 2013, MCKINSEY Senior Partner 2 updated MCKINSEY Senior Partners 1 and 3 and MCKINSEY Consultant 3: "Good long discussion. Feeling better about '13 than '12. FDA is moving in the right direction on label. … Eventually opened up a bit and could imagine help 'at the right time' to see if there is upside. …" MCKINSEY Senior Partner 3 replied that he would follow up with Purdue Pharma but that Purdue Pharma's head of sales was embarrassed after an earlier project "and even more frustrated that [the CEO] stopped the last oxy proposal." The same MCKINSEY partner wrote: "Wonder if there is a creative way to breakthrough – just feels like we could help them a lot."

92. On April 16, 2013, FDA approved a change in the labeling of OxyContin, and authorized the new formulation, as detailed above.

93. In early April 2013, Purdue Pharma Chief of Staff emailed MCKINSEY Senior Partner 1 to alert him that Purdue Pharma Executive 3 would be reaching out to discuss the OxyContin project that MCKINSEY had proposed one year prior.

94. By mid-April 2013, MCKINSEY shared the draft of its proposal to identify granular growth opportunities for OxyContin with Purdue Pharma Executive 4.

MCKINSEY indicated it was willing to move as swiftly as Purdue Pharma desired and wanted to work through the draft proposal together.

XI. MCKINSEY worked with Purdue Pharma to "Turbocharge" reformulated OxyContin sales and presented its recommendations to Purdue Pharma's Leadership: "the findings were crystal clear to everyone"

95. In May 2013, Purdue Pharma retained MCKINSEY to "conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities." This 2013 effort would come to be called "Evolve to Excellence," or "E2E," and included MCKINSEY advising Purdue Pharma on how to "turbocharge" the sales pipeline for OxyContin.

96. On May 24, 2013, Purdue Pharma Executive 10 emailed the MCKINSEY team that they should "consider modeling in the end a 'fight the fight' strategy versus a milking strategy just to cover all bases. What would each look like from a P&L basis."

97. MCKINSEY understood that part of its role was to empower those within Purdue Pharma's senior management who favored a more aggressive approach to sales and marketing of reformulated OxyContin—the "corrective action" that Family Member 1 had demanded in 2012. MCKINSEY took on this role despite knowing Purdue Pharma's troubled history, the 2007 CIA, and the dangers of OxyContin.

98. MCKINSEY consultants had interviewed Purdue Pharma personnel who described Purdue Pharma as a "law firm that occasionally sells drugs" in which personnel felt stymied by the involvement of lawyers with respect to what could be communicated to

customers, especially in terms of abuse deterrence. MCKINSEY later noted that Purdue Pharma's organizational mindset, behavior, and culture would have to evolve in order to "turbocharge" its sales engine.

99. On June 2, 2013, MCKINSEY Consultant 4 emailed the MCKINSEY team with notes from a discussion with Purdue Pharma Executive 4. She reported that Purdue Pharma Executive 4 "[g]ave us a full history of Oxy with [generics] entering in '04, Purdue Pharma reversing the court ruling, subsequently regaining share, launch of AD formulation, dropping share expectedly due to loss abuse . . . (made it sound like a cat with 9 lives)." MCKINSEY Consultant 4 also reported that Purdue Pharma Executive 4 believed "the pain market is 'flat and saturated' and that Oxy has no clinical differentiation and that is the normal life cycle of a product and Oxy is essentially on the decline but that they can ease that decline."

100. In an email dated June 3, 2013, MCKINSEY Consultant 4 forwarded an email to members of the MCKINSEY team (copying MCKINSEY Senior Partner 3) with a report that Pharmacy Chain 2 had stopped carrying OxyContin except for one location. The email chain, which originated from Purdue Pharma, included a comment from a pharmacist that "it is the one everyone abuses." MCKINSEY Consultant 4 responded: "guys. See note at bottom. Per previous email . . . 'is it the one everyone abuses'? there is a lack of market education and sophistication and Purdue Pharma 'potentially' has not kept the record straight but let's check that[.]"

101. In an email dated June 10, 2013, MCKINSEY Consultant 4 emailed the MCKINSEY team with a "brief update" from a Purdue Pharma Board meeting. MCKINSEY Consultant 4 wrote: "BoD appreciated the tougher environment . . . including significant issues at the pharmacy level / DEA activities and do believe there should be counter-messaging [I think this is likely PR, publications, plus education policy makers, agencies as well as customers]." Purdue Pharma's Board "want[ed] to understand the level of awareness within the declining prescribers and whether awareness impacts prescribing [think the latter is key since they have not done anything that would increase awareness at this point]." The same consultant added: "data generation is critical to both – creating an awareness that is compelling and counter-messaging in the current environment . . . generally hope that our work will inform these and what they can do about the shortfall."

102. On or about June 13, 2013, MCKINSEY Consultant 4 emailed the MCKINSEY team with a news article announcing Pharmacy Chain 1's $80 million settlement with the Department of Justice and DEA over civil charges that the company had practiced improper distribution of prescription painkillers. MCKINSEY Consultant 4 wrote to the MCKINSEY team: "think this is bad. When they say they have systems already in place to address, think they will make it onerous and annoying to get an Oxy script filled and they have probably scared the living daylights out of the pharmacists…we need to understand whether [other pharmacy chains] are next and invest in educating them how to truly prevent abuse and potentially to engineer around this issue . . . ." On the following day, MCKINSEY Consultant 4 further stated, when discussing this article, "since Purdue

wrote the book on abuse deterrence and pain, for example [*sic*], they should be able to bring something to the table in terms of teaching how to identify and prevent abuse in a more rationale [*sic*] manner (take the high road). But requires investment."

103. In a later email in the same chain, MCKINSEY Consultant 4 wrote that she wanted "to understand about the other chains. Do they plan to follow suit and how can [Purdue Pharma] blunt."

104. In an email in the same chain dated June 14, 2013, MCKINSEY Senior Partner 3 replied to the MCKINSEY team: "Indeed, v [*sic*] big issue. [MCKINSEY Consultant 4] and I discussed thinking about alternative distribution challenges, potentially eliminating retail pharmacy through creative partnership w a [specialty pharmacy]. …"

105. MCKINSEY's marketing strategy also focused on mitigating patient "access issues" (e.g., difficulty filling OxyContin prescriptions due to pharmacies' decision not to stock OxyContin; pharmacy-level restrictions on the quantity of units and length of use; or inability to fill due to high cost). For example, internal MCKINSEY discussions regarding patient access highlighted the need to promote the distribution of "savings cards in high-Pharmacy Chain 1's areas . . . ." Further, in a July 31, 2013 draft of a MCKINSEY presentation deck entitled, "OxyContin Growth Opportunities," MCKINSEY suggested Purdue Pharma "provide all 100 prescribers on target list with at least 1 starter kit (e.g. product information, pain tracker, savings card" and "[d]istribute OxContin [*sic*] savings cards with physicians with a high proportion of patients with Tier 3 access (and thus high

copay)." From August 2013 through 2019, Purdue Pharma redeemed more than 2.9 million OxyContin savings cards.

106. MCKINSEY consultants spoke with Purdue Pharma about the concerns and increasing reluctance of pharmacists and pharmacy chains to fill prescriptions for OxyContin. MCKINSEY also spoke directly to some of these pharmacists.

107. As part of the same project, MCKINSEY consultants went on several "ride-alongs" with Purdue Pharma sales representatives in the field, as these sales representatives called on prescribers and pharmacists. The information MCKINSEY gathered during these ride-alongs helped develop proposals to "turbocharge" the OxyContin sales engine and ways to address "the impact of distributors and pharmacies cutting back on their drug stocking[.]"

108. In notes about one of these ride-alongs, MCKINSEY Consultant 5 wrote, in part, "Pharmacist; [had] a gun and was shaking; abuse is definitely a huge issue[.]"

109. In an email dated July 12, 2013, MCKINSEY Consultant 4 emailed a Purdue Pharma sales representative whom MCKINSEY Consultant 4 had accompanied on a ride-along with a series of follow-up questions. These included: "Are pharmacies 'rationing' demand for OxyContin? In other words, given that certain distributors have cut back their buying and certain pharmacies have cut back their inventories, does that mean pharmacies will ration? . . . is it also possible have had to do this disproportionately for the higher doses?" MCKINSEY Consultant 4 explained: "Here we are trying to understand whether the trend downward in dosage strength can possibly be driven by pharmacists – and

whether pharmacists then are also calling doctors to ask them if they can dose down bc they have so little high doses[.]" MCKINSEY Consultant 4 also asked the Purdue Pharma sales representative if he could coordinate a call with one of the pharmacists that they called on during the ride along which operated an independent pharmacy.

110. On or about July 19, 2013, MCKINSEY Senior Partner 1 complained to Purdue Pharma's leadership that Purdue Pharma Executive 5, the most knowledgeable in-house counsel concerning abuse and diversion deterrence, was providing feedback identifying mistakes in MCKINSEY's data analysis, which MCKINSEY Senior Partner 1 said was "outside the process and criticizing the work product."

111. In an email dated August 4, 2013, MCKINSEY Consultant 5 emailed the MCKINSEY team about revisions to a presentation for Purdue Pharma Executive 1. MCKINSEY Consultant 5 noted Purdue Pharma Executive 1's earlier request that the presentation address "the rather marked reduction in the number of tablets per prescription that has occurred all across the long-acting opioid market" as well as "the reasons why the 80mg strength of OxyContin is declining in prescriptions so much more rapidly than are the lower strength tablets." MCKINSEY Consultant 5 indicated that some of the decline was due to "pharmacy actions," such as Pharmacy Chain 1's polices including "a tablet count red flag over 120 pills nationwide," as well as "other policies making upward titration more difficult." Other causes for the decline were "driven in part by state regulations such as W[ashington] requiring a referral to a pain specialist for any Rx over 120mg morphine equivalent (~60mg Oxy)."

112. On August 5, 2013, MCKINSEY Consultant 6 replied to MCKINSEY Consultant 5's email by recommending Purdue Pharma take "specific actions which if implemented typically deliver 5+% net revenue impact." These included: moving to "workload-based sales targeting to focus call effort on highest-potential prescribers;" requiring the sales force to "adhere to" the call lists; making "re-capturing the 'biggest losers' among prescribers an ongoing field imperative;" and immediately launching "sales pilots to test growth maximizing levers[.]"

113. Prior to August 8, 2013, documents prepared for Purdue Pharma referred to the need to "energize" or "rebuild" Purdue Pharma's sales engine and increase OxyContin sales. On August 8, 2013, MCKINSEY Senior Partner 3 proposed a change in wording for communications to Purdue Pharma: "Replaced Energize with 'Turbocharge.' Energize feels too Richard Simmons. Turbocharge at least evokes the notion of real construction."

114. On or about August 8, 2013, MCKINSEY provided Purdue Pharma with a confidential memorandum on "Identifying granular growth opportunities for OxyContin," with additional findings on "specific actions we believe [Purdue Pharma] should take to begin to increase sales." Among other things, MCKINSEY advised Purdue Pharma to "accelerate exploration of potential innovative alternatives such as direct-to-patient mail order[.]" This advice was a reaction to the steps brick-and-mortar pharmacies were taking to decrease diversion. In a later document, MCKINSEY suggested that this potential distribution channel should involve "verification of prescription and patient legitimacy,"

and could involve specialty pharmacies, or other operators, to help fulfill the role of a traditional brick-and-mortar pharmacy.

115. On August 12, 2013, MCKINSEY Consultant 7 emailed the MCKINSEY team with a link to an *LA Times* article concerning Purdue Pharma tracking of Region Zero prescribers. The same MCKINSEY consultant wrote that Purdue Pharma's federal lobbyist "mentioned this LA Times article as the latest to really get Purdue's attention."

116. The *LA Times* article began:

> Over the last decade, the maker of the potent painkiller OxyContin has compiled a database of hundreds of doctors suspected of recklessly prescribing its pills to addicts and drug dealers, but has done little to alert law enforcement or medical authorities. Despite its suspicions, [Purdue Pharma] continued to profit from prescriptions written by these physicians, many of whom were prolific prescribers of OxyContin. … [Purdue Pharma] has promoted the idea that the country's epidemic of prescription drug deaths was fueled largely by pharmacy robberies, doctor-shopping patients and teens raiding home medicine cabinets. The database suggests that [Purdue Pharma] has long known that physicians also play a significant role in the crisis.

117. Notwithstanding the *LA Times*' article, eight days later, on August 20, 2013, MCKINSEY gave Purdue Pharma a presentation with its proposed approach to "Turbocharging the Sales Engine" for OxyContin.

118. MCKINSEY's findings and recommendations for "growth opportunities for OxyContin" were reviewed by the Purdue Pharma Board. On August 15, 2013, Purdue Pharma Family Member 1 emailed fellow Family Member 2: "The 'discoveries' of

MCKINSEY are astonishing." Family Member 1 arranged for an in-person meeting with the Purdue Pharma Board and MCKINSEY, without Purdue Pharma's senior management present.

119. On or about August 23, 2013, MCKINSEY Senior Partners 2 and 3 and Consultant 6 met with certain members of the Purdue Pharma Board—all members of the Family—to present MCKINSEY's "unvarnished" findings and proposal.

120. In an email dated August 24, 2013, MCKINSEY Senior Partner 3 sent an update to the MCKINSEY team stating that they "took [the Family] through both memos – some had read it, some had not. We went through exhibit by exhibit for about 2 hrs. They all clearly learned a lot and many asked good questions." The same MCKINSEY Senior Partner further wrote: "They were extremely supportive of the findings and our recommendations. In fact, in closing, they summarized that they felt really good about all the opportunity we had found and wanted to strongly endorse getting going on our recommendations . . . . So a very good dialogue and an important milestone of impact . . . ."

121. MCKINSEY Senior Partner 2, another attendee, responded to the email that "[b]y the end of the meeting the findings were crystal clear to everyone and they gave a ringing endorsement of 'moving forward fast.'"

122. On or about September 11, 2013, MCKINSEY Consultant 6 emailed Senior Partner 3 and other MCKINSEY consultants about an FDA announcement concerning labeling for opioids. MCKINSEY Consultant 6 wondered of the announcement: "if high

writers even noticed this. :) ," "what portion of their current oxy patients (or all ER patients) are 'severe' vs. moderate to severe, what portion are 'as needed,'" and "if they think this will change their prescribing behavior (I'm guessing they'll say they already use it like this)."

123. Purdue Pharma chose to move forward with several elements of MCKINSEY's proposed "turbocharge" sales and marketing strategy, which was renamed "Evolve to Excellence," or "E2E," in September 2013. Purdue Pharma asked MCKINSEY to develop specific action steps, including assisting with coming up with a new approach to identifying which OxyContin prescribers to target for sales calls and at what frequency. According to a confidential memorandum from MCKINSEY to Purdue Pharma's CEO, dated September 16, 2013, MCKINSEY's fees and expenses for its work on E2E would be $795K per month, totaling $3.2 million through Purdue Pharma's National Sales Meeting in January 2014. All in, Purdue Pharma paid MCKINSEY $7,450,000.00 for its work on E2E.

124. On September 18, 2013, MCKINSEY Consultant 5 provided the "Final Reports" for E2E to Purdue Pharma. In the "Phase I Final Report: Diagnostic" slide deck, MCKINSEY provided a detailed overview of its work to evaluate many aspects of Purdue Pharma's opioid business including market landscape, demand forecast, messaging and positions, targeting, access and availability, scientific support, commercial spend levels, and patient funnels.

For the diagnostic phase of this engagement, MCKINSEY consultants did a deep dive into OxyContin's performance and the reasons for its declining sales. MCKINSEY consultants were aware of the existence of "pill mill" prescribers—that is, doctors and other prescribers who diverted high volumes of OxyContin while purporting to operate a legitimate medical practice. MCKINSEY consultants were also aware of efforts by states and law enforcement to crack down on abuse and diversion as one reason that certain wholesalers and pharmacies were no longer shipping or selling Schedule II medications to the public, including OxyContin. As part of this project, MCKINSEY consultants also went into the field on sales calls with Purdue Pharma sales representatives. In July 2013, MCKINSEY Consultant 5 went on a ride along, which included a visit to OxyContin Practice 1. While MCKINSEY Consultant 5 may not have known it, in fact, in 2010, OxyContin Prescriber 3, owner of OxyContin Practice 1, was reported to the North Carolina Medical Board. In 2010, OxyContin Prescriber 4, a physician assistant at OxyContin Practice 1, lost her license due to issuing prescriptions for opioids without a DEA registration. Although a ROC was submitted by a Purdue Pharma sales representative, OxyContin Practice 1 continued to be called on by Purdue Pharma. In September 2013, two months after MCKINSEY Consultant 5 visited, OxyContin Prescriber 3 entered into an interim non-practice agreement with the North Carolina Board of Medicine. In 2014, the Board of Medicine issued a Consent Order and OxyContin Prescriber 3 surrendered his license for improper opioid prescribing.

125. MCKINSEY's "Phase II Final Report" set forth its recommendations for Purdue Pharma, including sales targeting of High Value Prescribers and adherence to prescriber target lists by sales representatives. While Purdue Pharma had historically targeted physicians based only on the volume of extended-release opioids they were prescribing, MCKINSEY recommended that Purdue Pharma instead focus on High Value Prescribers using a series of additional factors including historic preference for generic drugs, willingness to change from one brand of drug to another, and medical specialty.

126. Ultimately, MCKINSEY developed a proposal for Purdue Pharma to try to stem the decline of OxyContin sales. A key piece of MCKINSEY's proposal was for Purdue Pharma to focus its marketing efforts—Purdue Pharma's sales force—on High Value Prescribers. It also recommended that Purdue Pharma mandate greater adherence by the sales force to prescriber target lists and give the sales force less freedom to choose which prescribers to call on. Through such "better targeting," MCKINSEY estimated that Purdue Pharma could reap "upside" of ">$100 million in annual sales." In an August 20, 2013 presentation, MCKINSEY wrote to Purdue Pharma that "75% of the decline in OxyContin sales comes from prescribers that it is not calling upon" – and 2/3 of that decline was from "prescribers in deciles[2] 5-10," i.e., the prescribers in the top five prescriber deciles. In September 2013, when MCKINSEY presented its key findings on targeting, it reiterated that "Analysis of sales force reach suggests calls are insufficiently focused on

[2] Purdue Pharma used deciles to divide up prescribing data to help analyze and prioritize marketing. A decile 10 prescriber would be among the highest prescribers for a particular drug or drug class.

high deciles" and that "Prescribers who do not receive calls account for 75% of the overall OxyContin decline." It further noted that "while reach is >70% for market decile 10, 9, and 8, it declines sharply for decile 7 (65% reach), decile 6 (57% reach), and decile 5 (47% reach)." MCKINSEY advised Purdue Pharma that by focusing the sales force on the top five decile prescribers; focusing their calls on OxyContin; and raising expectations for their "productivity," Purdue Pharma could "increase sales" by hundreds of millions of dollars.

127. As part of "turbocharging the sales engine" and rolling out the recommendations, MCKINSEY advised Purdue Pharma, among other things, to create a senior team to lead the effort, develop a detailed workplan within 30 days, and "refresh" the OxyContin sales messaging to prescribers.

128. MCKINSEY also stated there was an opportunity for a $220 million impact just from increasing calls on prescribers in deciles 5-10, making more of those calls with OxyContin as the primary detail, and requiring greater adherence by the sales force to prescriber target lists.

129. MCKINSEY's proposal to Purdue Pharma included a second key component: increasing sales of OxyContin in an environment where law enforcement, regulators, and others were attempting to address illegal prescriptions in the midst of an opioid crisis. In a confidential memorandum to Purdue Pharma's CEO and head of sales dated August 8, 2013, MCKINSEY referred to this as "retail access" (or "patients reporting difficulty filling opioid prescriptions"). MCKINSEY identified the "factors" impacting this

"access": "regulations, DEA initiatives, PROP[3], wholesaler initiatives, and local pharmacist perceptions."

130. MCKINSEY identified opioid guidelines adopted by major pharmacy chains as a challenge and focused on Pharmacy Chain 1 in particular. MCKINSEY wrote that Pharmacy Chain 1's national opioid dispensing guidelines were "quite extensive" and included "'flags' for new patients and dose limits which can clearly impact appropriate patient access." Pharmacy Chain 1's guidelines were modest measures in response to DEA efforts to crackdown on illegal and medically unnecessary opioid prescriptions. The "flags" were legitimate and recognized indicators of potential diversion.

131. For instance, the "flags" for OxyContin prescriptions included: if the quantity was 120 units or more; if the patient was on OxyContin for six months or more; if the patient lived far from the pharmacy; or if the prescription was paid for through cash/credit card rather than insurance.

132. MCKINSEY also told Purdue Pharma that as part of its agreement with the DEA, Pharmacy Chain 1 "eliminated controlled substances from their bonus calculations for pharmacists," such that "individual pharmacists lose money every time they accept the work of filling an opioid prescription."

133. Citing its "[d]eep examination of [Purdue Pharma's] available pharmacy purchasing data," MCKINSEY told Purdue Pharma that Pharmacy Chain 1's reduction in

[3] Physicians for Responsible Opioid Prescription, or "PROP," was a group that advocated for state and federal policies that encourage safe and responsible prescribing. They were a frequent critic of Purdue Pharma.

OxyContin purchases accounted for 50-70% of total OxyContin decline in units from March to June 2013. Moreover, MCKINSEY wrote that Pharmacy Chain 1's guidelines were having a "significant impact on higher OxyContin dosages," such as the drop-off in prescriptions for the 80 mg dose—the same trend that Purdue Pharma had identified with Region Zero prescribers following the OxyContin reformulation. MCKINSEY recommended two steps in response: "immediate action," including ensuring "appropriate senior level dialogue with Pharmacy Chain 1," and "accelerate exploration of potential innovative alternatives such as direct-to-patient mail order[.]" While MCKINSEY and Purdue Pharma characterized this effort as ensuring access for patients, in practice, these recommendations could, if implemented, blunt retail pharmacies and DEA's efforts to reduce diversion.

134. In an email dated September 23, 2013, Purdue Pharma Executive 1 sent an email to MCKINSEY stating: "the Executive Oversight Team has personally been assigned the task of tackling the company's conservativism and resistance to change – and for this is something that will for sure be taken up with the Board . . . . To support that effort will you please write-up several examples of where you feel our conservatism caused us not to pursue messaging (or other activities) that would have been helpful to the brand without (in your opinion) being non-compliant with the relevant laws and regulations."

135. In an email dated October 3, 2013, to Purdue Pharma's CFO, head of sales, and chief of staff to the CEO, MCKINSEY Senior Partner 3 identified eight "categories of conservatism," including that "brand investment is low relative to benchmarks," and that

"there is very limited investment in OxyContin, inclusive of next generation abuse deterrent technology." Other categories included, "Clinical education very limited education of physicians on developments in abuse deterrence (e.g., dinners);" and "Advocacy - limited development of physician and patient advocacy voices, at local and national level, to counter other stakeholders[.]" Purdue Pharma's chief of staff forwarded MCKINSEY Senior Partner 3's email to other Purdue Pharma executives to solicit their thoughts, writing: "what holds us back as a company is the general theme[.]"

136. MCKINSEY described for Purdue Pharma the value at stake: "hundreds of millions, not tens of millions." MCKINSEY pointed to prior analysis showing "over $200M of potential opportunity in a single year, even more in cumulative terms." The message resonated with Purdue Pharma. For instance, in an email dated September 19, 2013, about Purdue Pharma's 2014 budget, its CFO referred to "what some are calling the McKinsey $220 million stretch target. Yes – the McKinsey $220 million!"

137. On December 2, 2013, MCKINSEY received an email from Purdue Pharma which identified OxyContin as "still #1" on the list of the top 17 abused prescription drugs of 2013.

138. MCKINSEY focused on the value of OxyContin prescriptions to Purdue Pharma's bottom line. On December 4, 2013, MCKINSEY Consultant 5 emailed Purdue Pharma Executive 6 to request the "latest forecast that shows the 3-5 year projection for OxyContin and Butrans sales." MCKINSEY Consultant 5 added: "Trying to find ways to make the case for putting most of sales force effort behind OxyContin," as opposed to

Butrans, a Schedule III buprenorphine-based drug. Purdue Pharma Executive 6 replied with "the major talking points," including that the average sales value of an OxyContin script was 1.75 times that of Butrans. Purdue Pharma Executive 6 added that their "objective as a company is to profit optimize our sales calls. … In 2013 the sales value of OxyContin is $2.5 billion and the sales value of Butrans will be $145 million."

XII. MCKINSEY's role with E2E and reformulated OxyContin continued under new Purdue Pharma senior management

139. At the beginning of 2014, Purdue Pharma fired its CEO and replaced him with Purdue Pharma Executive 7. Shortly thereafter, Purdue Pharma also fired its two heads of sales. Nevertheless, MCKINSEY's role in launching the strategic initiatives of E2E continued.

140. MCKINSEY helped Purdue Pharma's senior management prepare for its National Sales Meeting in January 2014, including drafting documents for workshops and refining messages for the meeting. MCKINSEY took the lead in rolling out and educating the Purdue Pharma sales force on the E2E plan, creating background materials for use in "talk show" portions of the sales meetings and creating a detailed Q & A script in a taped interview to be viewed by the entire sales representative group.

141. In a presentation dated January 26, 2014, prepared for Purdue Pharma's National Sales Meeting, MCKINSEY explained the two objectives for OxyContin: (1) "Protect established business: Defend base by focusing on current high-writers;" and (2) "Prospect future business: Replenish [OxyContin prescriptions] by focusing on prescribers

with high likelihood of writing scripts for new patients . . . . The factors that are included in valuing physicians reflect [these goals]. For OxyContin, the targeting factors identified are: OxyContin TRx, Opioid market volume, New to Brand scripts, managed care access, and generic share of extended release opioids."

142. MCKINSEY worked with Purdue Pharma to develop a methodology to identify these High Value Prescribers as targets for increasing sales by using the commercially available IMS Prescriber data, the same commercially available data source that MCKINSEY had used to identify high writers for purposes of determining abuse and diversion in its geospatial project.

143. Based on factors selected by MCKINSEY, Purdue Pharma provided to its sales representatives lists of prescribers to whom Purdue Pharma would market OxyContin in person. These prescriber target lists included prescribers who previously had been reported internally within Purdue Pharma for abuse and diversion and, while not known to MCKINSEY, these prescriber target lists also included Region Zero prescribers.

144. During its diagnostic work for Purdue Pharma, MCKINSEY had reported to Purdue Pharma that in surveys of the sales force, at least one sales representative had reported the presence of Region Zero healthcare providers (HCPs), "We did have Region 0 HCP's on the list."

145. In October 2013, MCKINSEY noted that Purdue Pharma would remove Region Zero prescribers from its sale force prescriber target lists.

146. In an email dated January 14, 2014, MCKINSEY Consultant 8 emailed a Purdue Pharma senior sales manager with "a compiled list of feedback on the Q1 target list." Among the "feedback points" for Purdue Pharma to implement was that the call list clean-up project had not been fully implemented: "The target list still contains region 0 prescribers[.]"

147. In an email dated February 7, 2014, Purdue Pharma's South Florida district sales manager reported to the area sales manager that after reviewing her team's prescriber target lists, "it looks like there are 10-15% of targets that are not viable due to different reasons," including "sent to [ADD, Purdue Pharma's internal abuse and diversion detection program,] for review." The district manager identified a specific prescriber who had been reported to the ADD Program "a few times[.]"

148. The email was forwarded to the MCKINSEY consultants working on E2E and Purdue Pharma's senior sales management. Purdue Pharma's management explained to MCKINSEY that "[p]rescriber 'clean up' will be an on-going effort" and added: "Submitted to [ADD staff] (i.e., Region 0) – All legal approved region 0 prescribers were removed from the list of suggested targets. A submission to legal does not remove a prescriber, only those that legal places in region 0 are excluded."

149. During this time, MCKINSEY continued to communicate directly with senior executives of Purdue Pharma. On March 13, 2014, MCKINSEY Consultant 5 circulated to the MCKINSEY team his notes from a meeting with Purdue Pharma Executive 7, which he attended with MCKINSEY Senior Partner 1 and MCKINSEY

Consultant 6. MCKINSEY Consultant 5 wrote: "Don't take foot off pedal. Must deliver E2E. Critical for credibility with Board[.]" The next point: "Accelerate where we can[.]"

XIII. MCKINSEY'S multi-channel marketing advice to target no-see prescribers

150. As part of E2E, MCKINSEY worked with Purdue Pharma to evaluate so-called "multi-channel marketing," or ways to market OxyContin to prescribers who were part of networks or practices that the Purdue Pharma sales force could not call on for reasons including network or practice policies forbidding sales calls by pharmaceutical representatives (referred to as "no-see" prescribers).

151. In an email to Purdue Pharma employees, in which MCKINSEY provided Purdue Pharma a list of these "no-see" prescribers to target through multi-channel marketing, a MCKINSEY consultant stated "this is essentially a matrix to look at how many times we are reaching each no-see or limited-see physician. It also provides a way to see which prescribers we are not reaching at all (or only once), so that future programs can target those physicians." While MCKINSEY may not have known it, some of the prescribers on the list MCKINSEY provided to Purdue Pharma were on Region Zero.

152. In a presentation dated April 1, 2014, MCKINSEY wrote that these no-see prescribers represented a "significant portion of [Purdue Pharma]'s opportunity" to increase "reach and frequency." MCKINSEY proposed "new tactics" to "increase the frequency and impact" of Purdue Pharma's interactions with such prescribers, including "self-directed interaction." These included identifying the electronic medical record platforms (EMR) used by targeted no-see prescribers and advertising on those systems.

153. MCKINSEY and Purdue Pharma evaluated the "cost effectiveness" and "prescription lift" from such promotion. MCKINSEY sought out examples where a pharmaceutical company co-developed a clinical protocol for a system – for example, developing a screen for diagnosis that was built into clinical decision support and protocols.

154. MCKINSEY coordinated with Purdue Pharma to review internal data of health care providers who were characterized as no-see providers, which included physicians that were later convicted for illegal sales of prescription narcotics.

155. Purdue Pharma contracted with Practice Fusion as a partner for marketing OxyContin directly to prescribers. By 2016, Practice Fusion and Purdue Pharma had created a workflow to include a pain assessment in a clinical decision support message.

156. Through this arrangement, Purdue Pharma paid Practice Fusion kickbacks in exchange for using clinical decision support alerts within its EMR software to influence prescribers to prescribe more of Purdue Pharma's products, including OxyContin.

XIV. E2E Worked to Slow the Decline of OxyContin Prescriptions and Purdue Pharma's profits

157. MCKINSEY laid out options for how to motivate Purdue Pharma's sales force to carry out the E2E plan and maximize OxyContin prescriptions. One approach was MCKINSEY's so-called "wildfire" method, which involved identifying "champion reps" and using those "high performance reps to lead their own 'learning teams' of reps." The idea was to "[m]otivate champions and learning teams through competitions."

158. For Purdue Pharma and MCKINSEY, E2E was a financial success. Their targeting of High Value Prescribers slowed OxyContin's declining sales and kept Purdue Pharma's profits flowing. Purdue Pharma's sales force—which had been incentivized to carry out the E2E plan—shared in the success as well. In May 2014, Purdue Pharma issued individual bonus statements to its sales representatives for the first quarter of 2014. In a cover letter, Purdue Pharma's sales force executive director noted that "[o]ver 62% of representatives earned a 1st quarter bonus of $11,000 or greater" and an "OxyContin bonus of at least $5,000 was earned by 72% of representatives[.]" The letter added: "We believe that our performance that resulted in an above average payout is the result of a number of factors, but in particular improvements made in customer targeting and increased reach and frequency as a result of the E2E initiative . . . ."

XV. MCKINSEY's work on reformulated OxyContin continued with "FieldGuide"

159. After the conclusion of MCKINSEY's work for Purdue Pharma on E2E, MCKINSEY performed additional work with Purdue Pharma which also sought to maximize OxyContin sales by targeting sales efforts on High Value Prescribers.

160. In 2015, MCKINSEY designed "FieldGuide" as a product to license to pharmaceutical manufacturers. Purdue Pharma was to be its pilot partner. FieldGuide would help Purdue Pharma and its sales force, which Purdue Pharma had recently restructured to "more effectively promote Opioid products," including by "[q]uantifying field force structure" and "[e]valuat[ing] the quality of a sales call."

161. The FieldGuide project was an attempt to automate, through software, the type of sales targeting analysis that MCKINSEY conducted through E2E. As part of this project, MCKINSEY analyzed prescribing data for Purdue Pharma to determine connections (or "affiliations") between prescribers, and then presented its findings to Purdue Pharma. MCKINSEY's presentation, titled "Field Optimization", made clear that the targeted prescribers and clinics were writing very high volumes of OxyContin prescriptions.

162. On or about June 29, 2016, MCKINSEY presented to Purdue Pharma the results of its of its project, which stated: "There is opportunity to improve share in IDNs [Integrated Delivery Networks]/hospitals and large pain clinics with lower than average share."

163. MCKINSEY'S presentation emphasized that making "indirect calls" to other HCPs in an account "has a 20-30% impact on TRx for an HCP with the same affiliation – account calls are highly valuable due to this 'halo' effect." MCKINSEY stated: "Accounts with high-writers (e.g. pain clinics) are more responsive." These accounts included pill mills. This meant that even if an HCP was on Purdue Pharma's Region Zero list for suspected drug diversion, Purdue Pharma could still increase prescribing by promoting OxyContin to *other* HCPs at the same practice.

164. MCKINSEY again advised Purdue Pharma to "shift calls to accounts with high-writers and ensure 'total office' calls made to maximize impact." MCKINSEY further advised Purdue Pharma that such steps could have "a 10-15M potential impact."

165. For example, a June 2016 MCKINSEY presentation to Purdue Pharma included the following slide:

'GRANDPARENT' AFFILIATION

Top 20 'grandparent' accounts[1] by market volume

Specialist pain clinics Hospital systems / IDNs

Parent affiliation name	# HCPs	Market vol.[2]	Total Purdue TRx	Purdue portfolio ERO share, %
[redacted]	3,488	91,183	16,347	18
	4,044	75,729	14,415	19
	3,608	67,183	12,517	19
	90	58,776	11,857	20
	63	55,421	14,115	25
	2,365	52,170	9,163	18
	2,455	51,230	9,912	19
	2,647	46,921	9,507	20
	2,306	45,504	10,616	23
	1,900	44,246	8,350	19
	1,615	39,162	9,588	24
	3,155	36,103	6,199	17
	4,575	32,163	3,605	11
	1,777	30,820	7,755	25
	2,302	30,158	6,077	20
	10	28,964	11,935	41
	892	28,101	6,592	23
	951	27,400	4,705	17
	14	26,660	4,741	18
	1,261	26,563	5,609	21

1 Refers to highest available corporate affiliation in HCOS
2 Market opportunity defined as ERO TRx, 11 months ending Aug 2015

Dynamic list available in FieldGuide tool

SOURCE: IMS Xponent; Purdue affiliations; IMS HCOS data; Team Analysis

McKinsey & Company | 22

166. MCKINSEY identified smaller clinics that were writing more opioid prescriptions (and more OxyContin prescriptions) than entire hospital systems. Indeed, according to MCKINSEY, the high volume of prescriptions issued by these clinics made their prescribers top targets for Purdue Pharma. Based on their illegal prescribing, at least two of the prescribers from these clinics were criminally charged and convicted, while others lost their license.

167. For example, the 10 HCPs who worked at OxyContin Prescriber 1's clinic wrote almost 29,000 prescriptions for extended-release opioids (EROs), of which almost 12,000 were for OxyContin. That was more ERO prescriptions than the 1,261 HCPs at a university-affiliated teaching hospital wrote in that same period, and more than double the number of OxyContin prescriptions written by HCPs at the hospital. As MCKINSEY's chart made clear, the HCPs at OxyContin Prescriber 1's clinic wrote more OxyContin prescriptions than most of the hospital systems reviewed by MCKINSEY.

168. While MCKINSEY may not have known it, OxyContin Prescriber 1 was not added by Purdue Pharma to its Region Zero list until November 2014, despite multiple prior reports of concern (ROC) to Purdue Pharma's ADD Program. Even though the prescriber himself was finally placed on the list, Purdue Pharma sales representatives continued to detail other prescribers in OxyContin Prescriber 1's practice at least 1,500 times from October 2014 through May 2018.

169. In April 2016, OxyContin Prescriber 1 was charged in a 114-count federal indictment with operating a criminal conspiracy, issuing 300,000 illegal prescriptions in four years, and providing painkillers to patients without a legitimate medical reason. The indictment alleged that OxyContin Prescriber 1 set up a prescription-renewal process that resulted in 300 illegal renewals each day.

170. A few months before MCKINSEY's presentation that advised Purdue Pharma to target high volume prescribers, including, but not limited to, OxyContin Prescriber 1's clinic, a Purdue Pharma district sales manager submitted another troubling

report to ADD. In May 2016, this Purdue Pharma district manager submitted a report on OxyContin Prescriber 1's practice, citing concerns about the HCPs prescribing to patients on a rotating basis. The Purdue Pharma district manager also expressed concern that the practice was writing over 8,000 opioid prescriptions per week, "much of it our products."

171. In 2017, OxyContin Prescriber 1 was charged with additional counts in a superseding indictment that accused him of contributing to the death of six patients. OxyContin Prescriber 1 pled guilty and in 2020 was sentenced to 70 months in prison.

172. Another prescriber highlighted in MCKINSEY'S presentation was OxyContin Prescriber 2, owner of several pain clinics in Alabama. MCKINSEY identified him as a top Purdue Pharma customer in the Field Optimization presentation as a single practitioner writing as many prescriptions as much larger practices.

173. OxyContin Prescriber 2 was sentenced in 2020 for unlawfully distributing opioids.

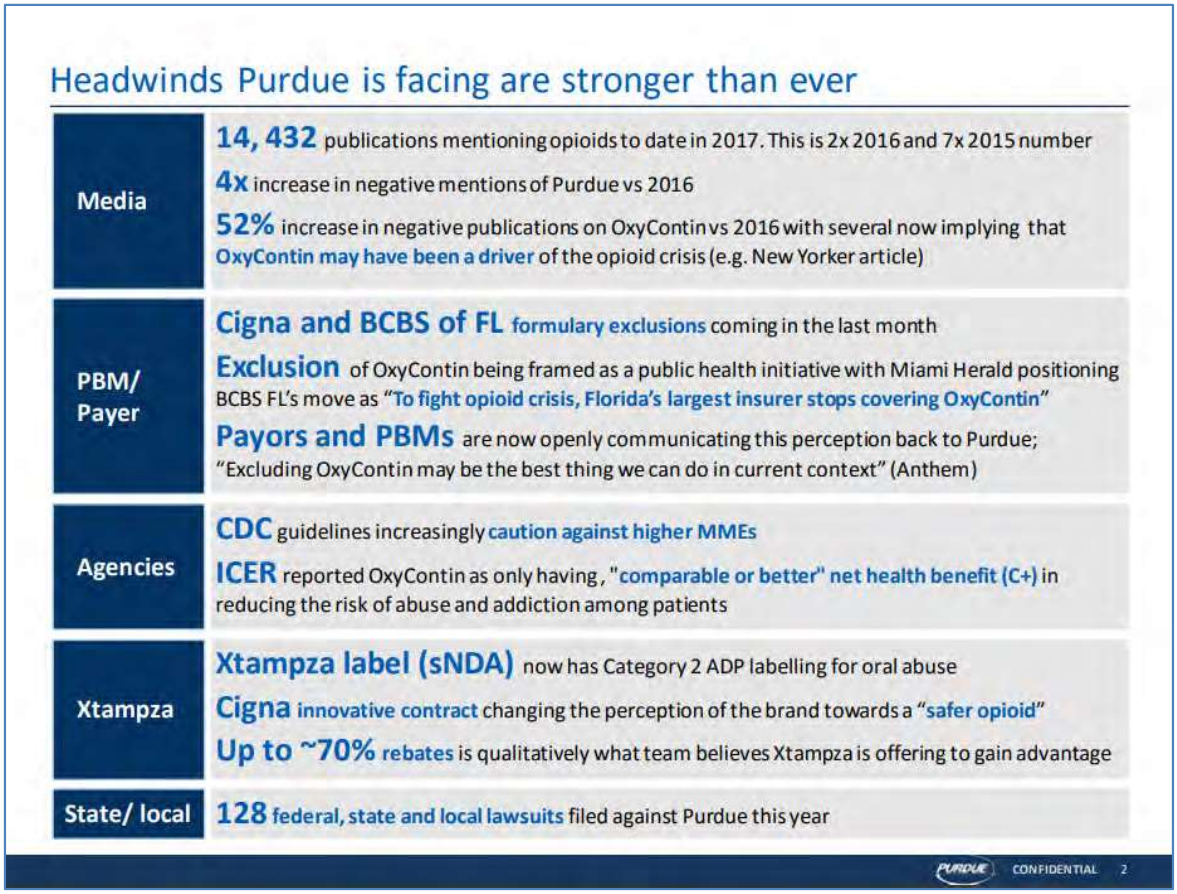
XVI. MCKINSEY keeps working on reformulated OxyContin with "market access" project

174. Health insurance companies threatened to stop paying for OxyContin or threatened to remove the drug from their formularies, the list of approved medications—an issue referred to under the heading of "market access."

175. MCKINSEY was engaged to work on "market access" for OxyContin in Fall 2017. For this assignment, MCKINSEY's work included developing potential alternative contracting strategies and developing a new "payor value story," i.e., changing the way

Purdue Pharma spoke to health insurers and pharmacy benefit managers. As part of the revised "payor value story," MCKINSEY urged Purdue Pharma to address and to counter the public narrative concerning the Family and OxyContin. While doing this work, on October 23, 2017, following a call with senior executives of Purdue Pharma, MCKINSEY Consultant 6 forwarded "a bunch of articles" to MCKINSEY Senior Partner 3 about the Family, and in particular an expose in *The New Yorker* magazine. (MCKINSEY Senior Partner 3 and MCKINSEY Consultant 6 were the same consultants who played a leading role in "turbocharging" the OxyContin sales pipeline during E2E.)

176. A MCKINSEY PowerPoint slide from November 28, 2017, summarized these "headwinds" that Purdue Pharma was facing:



177. One area of focus for MCKINSEY was on contracting—that is, the terms of the agreements between Purdue Pharma and payors—to ensure that payors would continue to include OxyContin on its formularies. MCKINSEY developed ideas for so-called "innovative contracts" between Purdue Pharma and payors, to show payors that their interests were aligned with Purdue Pharma and that they should therefore keep covering OxyContin.

178. In 2017, MCKINSEY proposed several options for innovative contracts, including contracts based on reducing the morphine milligram equivalents (MME) daily

dose. Reducing the MME daily dose means that a patient would be receiving a lower daily dose of opioids.

179. MCKINSEY also developed "event-based rebates" for Purdue Pharma to consider, which were done to reflect the trend that other pharmaceutical companies were offering for non-controlled substances. The event-based rebates would have Purdue Pharma pay insurance company payors a penalty (through a specified rebate) in the event of an OxyContin-related overdose. MCKINSEY told Purdue Pharma that in addition to helping maintain formulary status, these rebates would help "align incentives with payors to address the opioid crisis."

180. On November 16, 2017, MCKINSEY Consultant 9 emailed MCKINSEY Senior Partner 3 and MCKINSEY Consultant 6 in advance of a meeting with Purdue Pharma Executive 8. MCKINSEY Consultant 9 attached a series of PowerPoint slides, writing "want to see how 'bold' we should go in suggesting actions[.]" On one slide, MCKINSEY proposed offering a "[r]ebate given per OUD/OD incidence."[4] Under the heading, "How could we structure it?", MCKINSEY considered options based on "[p]er patient usage" ("rebate for volume of Rx for patient with event") and "[p]er cost" ("cover x% of medical costs associated with event").

181. In another MCKINSEY presentation to Purdue Pharma, in December 2017, MCKINSEY quantified the size of the penalty that Purdue Pharma should offer to pay for

[4] "OUD" stands for Opioid Use Disorder and "OD" stands for overdose.

OxyContin-related overdoses and instances of OxyContin-related OUDs. One slide included a proposed $7,000 rebate per OD/OUD, or "event," as MCKINSEY referred to it. MCKINSEY laid out "[i]mportant considerations" when determining such a rebate, including defining an "event rate." ("Today there are ~50 events of OxyContin-related OD/OUDs per million members per year and has grown 5% annually between 2014-16.") MCKINSEY added that "[m]eaningful rebate amounts per OD/OUD event can vary from ~$6k (cost of OxyContin) to ~$14k (excess medical costs)[.]"

182. As part of this "rebate" analysis, MCKINSEY calculated Purdue Pharma's potential costs if it paid for OxyContin-related overdoses affecting Purdue Pharma's top seven payor "accounts." MCKINSEY estimated that the range of the potential OD/OUD rebate would be $52.8 million to $123 million.

183. Purdue Pharma did not implement MCKINSEY's proposals.

XVII. MCKINSEY Senior Partner obstructs investigation by deleting Purdue Pharma documents

184. As scrutiny of Purdue Pharma's role with the opioid crisis increased, MCKINSEY consultants who worked with Purdue Pharma recognized that their client service to Purdue Pharma could become the subject of legal proceedings.

185. Text messages between MCKINSEY partners reflect caution about putting things in writing and concern about their emails surfacing in later Purdue Pharma litigation. In an iMessage exchange dated May 11, 2017, MCKINSEY Consultant 6 texted MCKINSEY Senior Partner 3 about emailing "opioid decks" to Purdue Pharma executives.

MCKINSEY Senior Partner 3 asked "what's bad in that deck…," to which MCKINSEY Consultant 6 replied: "Nothin [*sic*] bad. We said we wouldn't do it. And creates a trail to the inline discussion. These guys will be deposed. Best our emails are not sucked into it."

186. In February 2018, Purdue Pharma laid off its OxyContin sales force and stopped the in-person promotion of OxyContin to prescribers. On February 5, 2018, five days before Purdue Pharma publicly announced the sales force reduction, MCKINSEY Consultant 6 texted another MCKINSEY partner about the Purdue Pharma Board's decision and cautioned the partner about communicating about it in writing: "Don't want to create email trail but the board decided to pull all reps from OxyContin."

187. MCKINSEY Senior Partner 2 was a senior partner in the firm's PMP practice. MCKINSEY Senior Partner 2 earned a law degree from Harvard University before joining MCKINSEY in the early 1990s. The same senior partner was an executive committee member of MCKINSEY Analytics and a former leader of MCKINSEY's Consumer & Shopper Insights Practice in the Americas. MCKINSEY Senior Partner 2 oversaw the "consultant learning and leadership development program" for MCKINSEY's consultant staff worldwide.

188. MCKINSEY Senior Partner 2 was a senior member of MCKINSEY's client service team for Purdue Pharma. MCKINSEY Senior Partner 2 worked on and supervised MCKINSEY's engagements with Purdue Pharma throughout the relevant period, including the E2E engagement described above.

189. MCKINSEY Senior Partner 2 was not directed by MCKINSEY's managing partner or Shareholder's Council (board of directors) to take the actions described below. Nevertheless, MCKINSEY Senior Partner 2 was working within the scope of his employment at MCKINSEY in taking those actions and acted, at least in part, to benefit MCKINSEY.

190. On July 3, 2018, the *Financial Times* reported that a former Purdue Pharma Board member had been named in a lawsuit by the Massachusetts Attorney General's Office relating to Purdue Pharma's unfair and deceptive practices in its marketing of OxyContin.

191. The next day, on July 4, 2018, MCKINSEY Senior Partner 2 emailed Senior Partner 3 at his MCKINSEY email address under the subject line, "Howdy[.]" In the email, MCKINSEY Senior Partner 2 wrote the following: "Hope you're well. Can you send me your private email address. Want to send you a note." MCKINSEY Senior Partner 3 responded by providing his Gmail account address.

192. MCKINSEY Senior Partner 2 then emailed Senior Partner 3's Gmail address. MCKINSEY Senior Partner 2 wrote:

> Just saw in the FT that [a Purdue Pharma board member] is being sued by states attorneys general for her role on the [Purdue Pharma] Board. It probably makes sense to have a quick conversation with the risk committee to see ***if we should be doing anything other that [sic] eliminating all our documents and emails***. Suspect not but as things get tougher there someone might turn to us. [Emphasis added].

193. MCKINSEY Senior Partner 3 replied that same day: "Thanks for the heads up. Will do."

194. On July 24, 2018, MCKINSEY Senior Partner 3 emailed a MCKINSEY information technology (IT) staff member with the question: "how do i delete an email archive on lotus notes?"

195. On August 5, 2018, MCKINSEY Consultant 10 forwarded an article to Senior Partner 2 from *Politico* regarding the Western District of Virginia's previous investigation of Purdue Pharma in the early 2000s.

196. On August 22, 2018, the *New York Times* published an article bearing the headline "Snaring Doctors and Drug Dealers, Justice Dept. Intensifies Opioid Fight." MCKINSEY Senior Partner 2 had an active subscription to the *New York Times* on the date of the article's publication.

197. On August 22, 2018, MCKINSEY Senior Partner 2 emailed himself an apparent "to-do" list, with the subject line, "When home." The items listed included: "delete old pur [Purdue Pharma] documents from laptop[.]"

198. The Government's forensic analysis of MCKINSEY Senior Partner 2's MCKINSEY-issued laptop confirmed that MCKINSEY Senior Partner 2 removed materials related to MCKINSEY's work for Purdue Pharma from the laptop.

199. The forensic analysis also confirmed that on August 24, 2018, MCKINSEY Senior Partner 2 initiated the process to move the "Purdue Pharma" folder in his Outlook account to the "Deleted Items" folder.

200. On August 25, 2018, MCKINSEY Senior Partner 2 emailed himself the following "Remove Purdue folder from garbage."

201. The forensic analysis confirmed that on August 26, 2018, MCKINSEY Senior Partner 2 initiated the process to permanently delete items from the Outlook "Deleted Items" folder.

202. The forensic analysis further revealed that in or about or between April 2018 and September 2018, MCKINSEY Senior Partner 2 removed a folder titled, "Purdue" which included a subfolder entitled "Strategy" from his Windows operating system.

203. The forensic analysis further showed that the removed Purdue Pharma folder contained more than 100 items, many of which appear to be dated in critical timeframes, both before and after the initial Purdue Pharma guilty pleas.

204. Seven of these documents include the name of the Purdue Pharma CEO at the time of the origination of the Purdue Pharma engagements with MCKINSEY. This individual was among the former Purdue Pharma executives who pled guilty and was convicted of misbranding in 2007.

205. The Windows operating system was installed on MCKINSEY Senior Partner 2's MCKINSEY-issued laptop on November 25, 2017. There is no Outlook event log activity reflecting that MCKINSEY Senior Partner 2 permanently deleted any items from November 25, 2017 to August 26, 2018, which indicated that such deletion was not his typical practice.

206. In October 2018, MCKINSEY Senior Partner 2 noted MCKINSEY's new policy to restrict use of work devices to work and he requested that a friend switch to his personal account for an email conversation.

207. MCKINSEY Senior Partner 2 was aware of investigations into Purdue Pharma's conduct and knowingly deleted both system and Outlook Purdue Pharma folders and related emails from his MCKINSEY laptop and in doing so, deleted documents that would have been pertinent to those investigations.

208. MCKINSEY received its first subpoena from the Department of Justice regarding opioid matters on February 25, 2019.

209. On February 3, 2021, following MCKINSEY's partner disciplinary process, MCKINSEY terminated the employment of MCKINSEY Senior Partner 2 and MCKINSEY Senior Partner 3.

XVIII. MCKINSEY Partner's Concurrent Engagement with Purdue Pharma and FDA

210. In May 2008, the FDA launched the Sentinel Initiative. The purpose of the Sentinel Initiative is to monitor the safety of FDA-regulated products, including all prescription drugs, vaccines, biologics, and medical devices. According to the FDA, the Sentinel Initiative has developed the largest multisite distributed database in the world dedicated to medical product safety.

211. During the 2010s, MCKINSEY worked on several projects for the FDA. These projects generally focused on process improvements, organizational restructuring, and technology enablement, not specific companies or products.

212. In or about December 2013, MCKINSEY sent a white paper to the FDA presenting a preliminary assessment of the Sentinel Initiative.

213. In or about March 2014, in follow-up communication regarding the Sentinel Initiative, MCKINSEY told the FDA that MCKINSEY had the following conflict-of-interest policy:

> It is McKinsey's long-standing policy to serve competing clients and clients with potentially conflicting interests as well as counter-parties in merger, acquisition and alliance opportunities, and to do so without compromising McKinsey's professional responsibility to maintain the confidentiality of client information. To avoid situations of potential conflict, consultants serving FDA will not be assigned to a competitively sensitive project for a significant period of time (typically two years) following an assignment for FDA.

214. In or about June 2014, the FDA awarded MCKINSEY the first in a series of contracts to conduct interim and final assessments evaluating the strengths, limitations, and appropriate uses of the Sentinel Initiative for informing regulatory actions in response to safety issues (the "Sentinel Assessment Project").

215. In or about November 2014, as part of the Sentinel Assessment Project, MCKINSEY consultants held a workshop with FDA personnel. The objectives of the workshop were to understand and internalize perspectives on current Sentinel use from

stakeholder interviews and survey results, prioritize and identify owners to increase Sentinel adoption, and discuss an implementation approach.

216. In or about February 2015, as part of the Sentinel Assessment Project, MCKINSEY consultants provided the FDA with a written interim assessment. The interim assessment focused on the public health impact of Sentinel to date and the achievement of milestones related to Sentinel. In or about September 2015, the FDA made that interim assessment publicly available on the internet.

217. In or about December 2015, MCKINSEY consultants – one of whom had co-led the Sentinel Assessment Project, including the above-referenced white paper, workshop, and interim assessment – met with Purdue Pharma's head of drug research and development to discuss Purdue Pharma's potential research and development of a new drug that, if developed and approved, would be subject to monitoring under the Sentinel Initiative.

218. In or about May 2016, MCKINSEY consultants internally discussed making a business pitch to Purdue Pharma, to advise it on strategies for using drug-related data analytics. One of these MCKINSEY consultants suggested that in the business pitch to Purdue Pharma, MCKINSEY highlight a particular MCKINSEY consultant's ongoing work on the Sentinel Assessment Project and offer that consultant's expertise to Purdue Pharma, because that consultant's knowledge of the Sentinel Initiative "would be v[ery] useful for them in opioids."

219. In or about September 2017, as part of the Sentinel Assessment Project, MCKINSEY consultants provided the FDA with a written final assessment. This assessment addressed a range of topics including (among others) finalizing organizational realignment; enhancing tools; onboarding new data partners; strengthening the integration of Sentinel into the regulatory decision-making process; and expanding Sentinel's capabilities to assess potential safety issues.

220. In or about December 2017, MCKINSEY consultants provided Purdue Pharma with a written proposal on how to cut costs in areas including (among others) data management and regulatory compliance. Purdue Pharma accepted MCKINSEY'S proposal and hired MCKINSEY. As part of that project, a MCKINSEY consultant who had co-led the Sentinel Assessment Project – including the above-referenced white paper, workshop, interim assessment, and final assessment – spent all day on January 3, 2018, and part of the day on January 4, 2018, at Purdue Pharma's corporate headquarters advising Purdue Pharma on how to cut costs.

221. In or about February 2018, MCKINSEY consultants – one of whom had co-led the Sentinel Assessment Project, including the above-referenced white paper, workshop, interim assessment, and final assessment – had another meeting to discuss a proposal to Purdue Pharma, for Purdue Pharma to research and develop a new drug that, if developed and approved, would be subject to monitoring under the Sentinel Initiative.

222. MCKINSEY submitted three invoices to the FDA for the Sentinel Assessment Project, and the FDA paid MCKINSEY $5,092,242.46 in satisfaction of those invoices.

223. Under MCKINSEY policy, as represented to the FDA, to avoid a conflict of interest and the appearance of a conflict of interest, a consultant typically would not be assigned to a competitively sensitive project until two years had passed.

224. MCKINSEY did not inform the FDA that any MCKINSEY consultant worked on any of the above-referenced projects for Purdue Pharma around the same time (s)he worked on the Sentinel Assessment Project. MCKINSEY does not admit that the above-referenced projects for Purdue Pharma were competitively sensitive with the Sentinel Assessment Project, but maintains that they were not competitively sensitive.

225. The parties stipulate and agree the facts set forth in this Statement of Facts are true and correct.

MCKINSEY stipulates and agrees the facts set forth in the Agreed Statement of Facts are true and correct:

McKinsey & Company, Inc. United States:

BY: _____ 12/10/24
Jonathan B. Sbonim — Date
Deputy General Counsel
Head of Legal, Americas
Partner of McKinsey & Company, Inc.
Vice President of McKinsey & Company, Inc. United States
Authorized Corporate Representative of McKinsey & Company, Inc. United States

McKinsey & Company, Inc.:

BY: _____ 12/10/24
Pierre M. Gentin — Date
Chief Legal Officer
Senior Partner of McKinsey & Company Inc.
Authorized Corporate Representative of McKinsey & Company, Inc.

Counsel for McKinsey & Company, Inc. United States and McKinsey & Company, Inc.:

_____ 12/10/24
Charles E. Duross — Date
Brian K. Kidd
Katherine E. Driscoll
Morrison & Foerster LLP

_____
James L. Bernard
Hogan Lovells US LLP

_____
Ingrid S. Martin
Todd & Weld LLP

The United States Attorney's Office for the Western District of Virginia:

BY: _____ December 13, 2024

Christopher R. Kavanaugh — Date
United States Attorney

KRISTEN M. ECHEMENDIA
Senior Trial Counsel
Department of Justice, Civil Division
Commercial Litigation Branch

RANDY RAMSEYER
Assistant United States Attorney

KIMBERLY M. BOLTON
Special Assistant United States Attorney
Assistant Attorney General
Medicaid Fraud Control Unit
Virginia Office of the Attorney General

KRISTIN L. GRAY
Special Assistant United States Attorney
Assistant Attorney General
Medicaid Fraud Control Unit
Virginia Office of the Attorney General

The United States Attorney's Office for the District of Massachusetts:

BY: _____

Joshua S. Levy
United States Attorney

AMANDA MASSELAM STRACHAN
Chief, Criminal Division

WILLIAM B. BRADY
Assistant United States Attorney

The United States Department of Justice, Consumer Protection Branch:

BY: Amy Deline For
Amanda N. Liskamm
Director

Amy Deline For
Anthony Nardozzi
Deputy Director, Criminal

Amy Deline
Amy L. DeLine
Assistant Director

JESSICA C. HARVEY
Trial Attorney

STEVEN R. SCOTT
Trial Attorney